IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Caroline Polt and Monica Polt, individually and as co-executors of the estate of Joanne Polt, deceased,	:	CIVIL ACTION NO. 16-2362
Plaintiffs,	:	
v.	:	
Sandoz, Inc.,	:	
Defendant.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. May 26, 2020

Table of Contents

I. INTRODUCTION

Caroline and Monica Polt, individually and as co-executrixes of the estate of Joanne Polt, (hereinafter "the Polts") bring this action against Sandoz, Inc., (hereinafter "Sandoz") claiming that its failure to directly warn their mother Joanne Polt about the risks associated with taking the drug it manufactured caused her death. The Polts claim that, under Pennsylvania law, Sandoz owed a duty to Joanne Polt to deliver to her a medication guide accompanying the drug, in accordance with FDA regulations. Sandoz responds that a claim for failure to warn a consumer directly is preempted by federal law. The issue is whether Pennsylvania recognizes an independent cause of action for failure to warn a consumer directly of the risks associated with the medically prescribed drug. If, indeed, there is this duty to warn under Pennsylvania law, the claim is not preempted. If there is no such duty, then the claim is preempted.

The Court concludes that the Polts' claim is preempted. Under the learned intermediary doctrine, a drug manufacturer has no duty to warn the consumer directly about the risks associated with its drug when it had warned the consumer's physicians. In this case, Sandoz warned Joanne Polt's physicians. And neither an exception to nor an abandonment of the learned intermediary

doctrine, which has been strictly and consistently applied in Pennsylvania for fifty years, is appropriate in this case.

II. FACTUAL BACKGROUND

The Polts' mother, decedent Joanne Polt, died from pulmonary fibrosis. She had taken Sandoz's drug, amiodarone, over a five-year period. The FDA approved amiodarone as a drug of last resort to treat life-threatening ventricular fibrillation and ventricular tachycardia. But physicians sometimes prescribed it "off-label"[1] to treat non-life-threatening atrial fibrillation. In Joanne Polt's case, she was prescribed the drug for atrial fibrillation, an off-label use. After five years of amiodarone use, she was diagnosed with pulmonary fibrosis. Pulmonary fibrosis is a disease associated with pulmonary toxicity, a known adverse side effect of amiodarone. Joanne Polt died shortly after this diagnosis.

Sandoz is a generic manufacturer of amiodarone and provides to physicians the same warning label as is provided by the brand-name manufacturer of amiodarone. As a generic manufacturer, under FDA regulations, Sandoz has a duty of sameness, which means that its warning label for amiodarone must be the same as the brand-name manufacturer's warning label.

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[1] Prescribing a medication for off-label use means to prescribe it to treat an illness other than the illness it was approved to treat. See In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 240 (3d Cir. 2012) ("Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses.").

Sandoz complied with this duty. And this amiodarone warning label includes a warning of the risk of pulmonary toxicity.

Sandoz is also required by FDA regulations to warn consumers directly. In addition to the warning label given to physicians, it must provide pharmacies with "medication guides"[2] to give directly to consumers. The Polts contend that Sandoz did not comply with these FDA medication guide regulations.

The Polts also contend that Sandoz failed to provide a warning to Joanne Polt's physicians. At least three different physicians provided care to Joanne Polt, but the Polts only point to the testimony of Dr. Cox, her cardiologist, as creating a dispute of fact on this issue. Dr. Cox testified that he was aware that amiodarone could lead to pulmonary toxicity. But he was not aware that amiodarone was a drug of last resort. And he was not aware that it was only approved by the FDA to treat ventricular tachycardia and ventricular fibrillation. Dr. Cox was also not aware that a medication guide was required for amiodarone, and he testified that a medication guide provided to Joanne Polt, but not to him, would have assisted him in conveying information about the drug.

[2] Medication guides are paper handouts that the FDA requires to accompany certain medications. See FDA, Medication Guides (Jan. 3, 2020), https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm (last visited May 21, 2020).

The Polts brought this action for wrongful death, alleging negligent failure to warn, negligence per se, and negligent marketing. Sandoz moved to dismiss all counts on preemption grounds, and this Court granted the motion as to the negligent marketing count, but denied the motion as to the negligent failure to warn and negligence per se counts. This Court reasoned that the Polts might be able to defeat preemption if they could show that the negligent failure to warn and negligence per se claims are based on state tort law imposing a duty on the manufacturer to warn consumers directly, but could not show that the negligent marketing claim was based on anything other than the federal regulations. Following extensive discovery, the parties now bring motions for summary judgment, mainly contesting whether the negligent failure to warn and negligence per se claims are based on state tort law independent of federal law. The parties do not dispute that Pennsylvania substantive law applies.

Sandoz and the Polts also submitted motions in limine seeking to exclude expert testimony, but the Court need not rule on these motions because, in accordance with the suggestion of the parties, it is not necessary to do so to resolve the motions for summary judgment. Thus, only Sandoz's motion for summary judgment and the Polts' two cross-motions for partial summary judgment are discussed below.

III. LEGAL STANDARD

Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "A motion for summary judgment will not be defeated by 'the mere existence' of some disputed facts, but will be denied when there is a genuine issue of material fact." Am. Eagle Outfitters v. Lyle & Scott Ltd., 584 F.3d 575, 581 (3d Cir. 2009) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986)). A fact is "material" if proof of its existence or nonexistence might affect the outcome of the litigation, and a dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248.

The Court views the facts in the light most favorable to the nonmoving party. "After making all reasonable inferences in the nonmoving party's favor, there is a genuine issue of material fact if a reasonable jury could find for the nonmoving party." Pignataro v. Port Auth. of N.Y. & N.J., 593 F.3d 265, 268 (3d Cir. 2010). While the moving party bears the initial burden of showing the absence of a genuine issue of material fact, meeting this obligation shifts the burden to the nonmoving party, who must "set forth specific facts showing that there is

a genuine issue for trial." Anderson, 477 U.S. at 250 (quoting Fed. R. Civ. P. 56).

The standard for summary judgment is identical when addressing cross-motions for summary judgment. Lawrence v. City of Philadelphia, 527 F.3d 299, 310 (3d Cir. 2008). When confronted with cross-motions for summary judgment, "[t]he court must rule on each party's motion on an individual and separate basis, determining, for each side, whether a judgment may be entered in accordance with the Rule 56 standard." Schlegel v. Life Ins. Co. of N. Am., 269 F. Supp. 2d 612, 615 n.1 (E.D. Pa. 2003) (quoting 10A Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2720 (3d ed. 1998)).

IV. DISCUSSION

The application of the learned intermediary doctrine resolves the core of all the summary judgment motions in favor of Sandoz. Under this doctrine, Sandoz's state law tort duty is to warn physicians, not the ultimate consumers. While the Polts argue for an exception to the learned intermediary doctrine, none is available under the facts of this case. And the Court will not ignore or abandon this doctrine, which is firmly established in Pennsylvania.

A. Sandoz's Motion for Summary Judgment

The Polts bring three claims, under failure to warn and negligence per se theories: (1) Sandoz failed to warn physicians

at all, (2) Sandoz failed to adequately warn physicians, and (3) Sandoz failed to directly warn consumers in accordance with FDA medication guide regulations. The third claim is the true crux of the dispute, and the other two claims are peripheral contentions, argued half-heartedly and as alternatives.

And while their third claim merits a robust discussion of the issues involved, all three claims decidedly fail. As to the first, that Sandoz failed to warn physicians at all, although it is not preempted, it fails because there is no genuine dispute that the physicians were aware of the risk of pulmonary toxicity. As to the second, that Sandoz failed to adequately warn physicians, it is preempted because federal law requires Sandoz, as a generic manufacturer, to use the brand-name manufacturer's warning label. As to the third, that Sandoz failed to warn consumers directly, it is preempted because it is not cognizable under state tort law in that Pennsylvania has adopted the learned intermediary doctrine, which applies without exception here.

1. Preemption

Two of the Polts' three claims are preempted. The claim that Sandoz did not provide any warning to physicians is not preempted. But the claim that Sandoz did not provide an adequate warning to physicians and the claim that Sandoz did not

provide a medication guide to consumers are barred by implied preemption.

Under the Supremacy Clause of Article VI of the United States Constitution, federal law preempts state law in three ways: express preemption, implied preemption, and field preemption. Hillsborough Cty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985). Only implied preemption is at issue here.

Drug product liability claims are not preempted by express or field preemption. There is no express preemption clause in the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., that applies to prescription drugs. Riegel v. Medtronic, Inc., 552 U.S. 312, 327 (2008). And field preemption does not apply to claims for drug products liability because the FDCA does not occupy the field of drug safety oversight. See Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1677 (2019) (noting that Congress's purpose in enacting the FDCA was not to make the FDA the exclusive mechanism for maintaining drug safety).

But the FDCA may preempt a drug product liability claim by one of the two types of implied preemption: obstruction or impossibility. Wyeth v. Levine, 555 U.S. 555, 568, 573 (2009). It is true that there is a presumption against preemption in areas that are traditionally within the states' police powers,

such as health and safety. Bruesewitz v. Wyeth Inc., 561 F.3d 233, 240 (3d Cir. 2009). Yet a state law claim that "stands as an obstacle to Congressional objectives" will be preempted. Id. at 239. And, similarly, a state law claim will be preempted if it is "impossible for a private party to comply with both state and federal requirements." Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013) (quoting English v. General Elec. Co., 496 U.S. 72, 79 (1990)).

The claim that Sandoz did not provide any warnings at all to physicians is not preempted. This claim is not preempted because there is no conflict between federal and state law in that both require drug manufacturers to provide the warning label to physicians. See Eckhardt v. Qualitest Pharm., Inc., 751 F.3d 674, 679 (5th Cir. 2014) ("As failing to provide FDA-approved warnings would be a violation of both state and federal law, this is a parallel claim that is not preempted."). Thus, compliance with both federal and state law is not impossible, and compliance with state law does not obstruct federal law.

But the claim that Sandoz provided an inadequate warning to physicians is preempted by implied preemption through impossibility. It is well-settled that a claim based on a generic manufacturer's inadequate warning label is preempted by impossibility preemption because a generic manufacturer, under the FDA's sameness requirement, cannot unilaterally change a

drug's warning label. PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011).[3] Here, the Polts' claim that the warning label did not adequately warn physicians is preempted because it was impossible for Sandoz to both change the label to make it adequate under state law and comply with FDA regulations requiring the generic manufacturer's label to be identical to the brand-name manufacturer's label.

And finally, the claim that Sandoz did not provide warnings directly to consumers—in the form of medication guides—is preempted by implied preemption through obstruction. A state law claim that is parallel to an FDA requirement obstructs federal law if the claim is dependent on the federal requirement, but it does not obstruct federal law if it is independent of the federal requirement. See In re Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 792 (3d Cir. 1999).[4] Thus, because state tort law generally does not recognize a cause of action for a drug manufacturer's failure to

[3] See also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II), 751 F.3d 150, 165 (3d Cir. 2014) (noting that a claim based on the generic manufacturer not changing the drug's label is preempted where the "manufacturers have no control over the design or labeling of generic drugs").

[4] Compare Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353, 349-50, 353 (2001) (holding that where the "claim exist solely by virtue of the FDCA" it "exert[s] an extraneous pull on the scheme established by Congress" because private actions, having no regard for the "difficult (and often competing) objectives" of the FDA, will "inevitably conflict with the FDA's responsibility to [enforce] consistently with the [FDA]'s judgment and objectives"), with Wyeth v. Levine, 555 U.S. 555, 574, 579 (2009) (holding that the "widely available state rights of action" do not "pose[] an obstacle to [the FDCA's] objectives," but instead "offer[] an additional, and important, layer of consumer protection that complements FDA regulation").

warn consumers directly, "the majority of the district courts to consider this very [medication guide preemption] issue have found identical claims preempted." McDaniel v. Upsher-Smith Labs., Inc., 893 F.3d 941, 946 (6th Cir. 2018). These cases analyze whether there is an underlying state tort duty and make the preemption decision based on the existence or absence of this duty.[5]

Therefore, in this case, whether the Polts' medication guide claim is preempted depends upon what duty to warn Pennsylvania law imposes on drug manufacturers. It is to that question that the Court now turns.

2. State Law Duty

In Pennsylvania, when the "drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971), abrogated on other grounds by Kaczkowski v. Bolubasz, 421 A.2d 1027 (Pa. 1980). This doctrine is predicated upon the recognition that the physician, with his medical

[5] See Moore v. Zydus Pharm. (USA), Inc., 277 F. Supp. 3d 873, 881 (E.D. Ky. 2017) (holding that the claim was preempted because it "exists exclusively due to the federal regulatory scheme"); Marvin v. Zydus Pharm. (USA) Inc., 203 F. Supp. 3d 985, 989 (W.D. Wis. 2016) (holding that the claim was not preempted because it "is a tort law claim based on defendant's alleged failure to warn"); Perdue v. Wyeth Pharm., Inc., 209 F. Supp. 3d 847, 852 (E.D.N.C. 2016) ("Buckman requires more, however, than the existence of a general state law principle providing a cause of action for violation of a health and safety statute.").

expertise, is best positioned to "use his independent medical judgment" to decide "whether to prescribe a given drug" and to explain the risks and benefits of the drug "to the patient in the context of his or her individual medical circumstances." Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991) (quoting Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374, 378 (Pa. Super. Ct. 1987)). And this "[learned intermediary doctrine] is strictly applied by Pennsylvania courts." Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 545 (E.D. Pa. 2006), aff'd, 521 F.3d 253 (3d Cir. 2008), judgment vacated on other grounds, 556 U.S. 1101 (2009).

Other jurisdictions have adopted "limited exceptions to the learned intermediary doctrine" for (1) vaccines, (2) oral contraceptives, (3) contraceptive devices, (4) drugs marketed to consumers directly, (5) drugs that are over-promoted, and (6) drugs that are removed from the market. Vitanza v. Upjohn Co., 48 F. Supp. 2d 124, 130–131 (D. Conn. 1999), aff'd, 271 F.3d 89 (2d Cir. 2001). So far, Pennsylvania has only recognized the over-promotion exception. Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984).

The Polts do not contend that a recognized exception applies in this case.[6] Instead, they ask the Court to craft a

[6] At most they argue that there is an analogy here to the direct-to-consumer advertising exception. But this argument fails because even if Pennsylvania were to adopt the direct-to-consumer advertising exception, the

new exception, under Pennsylvania law, based on FDA regulations. The Court will reject this suggestion for three reasons: (1) it would break new ground and significantly expand liability under Pennsylvania law; (2) even if adopted, it would be inapplicable in this case; and (3) it would be a misuse of negligence per se, which does not operate to create a new duty.

i. Pennsylvania's Policy Against Expanding Tort Liability

An expansion of tort liability in this case would break with Pennsylvania's stated policy. Where "there [is] no reported decision by the Pennsylvania Supreme Court or any other Pennsylvania court addressing the precise issue before [the Court], it [is] the duty of the District Court to predict how the Pennsylvania Supreme Court would [rule] if presented with this case." Nationwide Mut. Ins. Co. v. Buffetta, 230 F.3d 634, 637 (3d Cir. 2000). In predicting how the Pennsylvania Supreme Court would rule, the Court "consider[s] relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue." Nationwide Ins. Co. v. Resseguie, 980 F.2d 226, 230 (3d Cir.

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reasoning for that exception does not apply here where it is not the case that "patients enter physicians' offices with 'preconceived expectations about treatment because of information obtained from DTC [direct-to-consumer] advertisements.'" See Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1260, 1263-64 (N.J. 1999) (quoting Tamar V. Terzian, Direct-to-Consumer Prescription Drug Advertising, 25 Am. J.L. & Med. 149, 157 (1999))).

1992) (quoting McKenna v. Ortho Pharmaceutical Corp., 622 F.2d 657, 663 (3d Cir. 1980)). And in making this prediction, "[f]ederalism concerns require that [federal courts] permit state courts to decide whether and to what extent they will expand state common law." City of Philadelphia v. Lead Indus. Ass'n, Inc., 994 F.2d 112, 123 (3d Cir. 1993); accord Vargus v. Pitman Mfg. Co., 675 F.2d 73, 76 (3d Cir. 1982) ("We have been asked to deliver prematurely a new doctrine of Pennsylvania tort law, and as a federal court we are unwilling to do so."); see 19 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 4507 (3d ed. 1998) ("In the same vein, it is not the function of the federal court to expand the existing scope of state law.").

Pennsylvania courts have generally "expressed reluctance to judicially expand tort liability on public policy grounds as such is properly the role of the legislature." Excavation Techs., Inc. v. Columbia Gas Co. of Pennsylvania, 936 A.2d 111, 121 (Pa. Super. Ct. 2007), aff'd, 985 A.2d 840 (Pa. 2009). And specifically, Pennsylvania has displayed a "general reluctance to expand tort liability within the [drug products] distribution chain." White v. Weiner, 562 A.2d 378, 385 (Pa. Super. Ct. 1989).[7]

[7] See Charles Shaid of Pennsylvania, Inc. v. George Hyman Const. Co., 947 F. Supp. 844, 855 (E.D. Pa. 1996) ("A sound and viable tort system—generally what we now have—is a valuable incident of our free society, but we must

Therefore, under the facts of this case, the Court will decline the invitation to alter Pennsylvania's social policy calculus as it relates to the liability of manufacturers engaged in the sale of prescription drugs. The crafting of an exception to the learned intermediary doctrine, if one is to be crafted at all, is best left to the legislature and Pennsylvania courts.

ii. The FDA Regulations Exception

Even if Pennsylvania were to adopt an FDA regulations exception, this exception, as it exists in all but one of the few jurisdictions that have adopted it, would not apply in this case. An FDA regulations exception would be an extension of the contraceptives exception. It would only be available where, in addition to regulations mandating direct-to-consumer warnings, it is foreseeable that a physician would not play the traditional learned intermediary role. This was not foreseeable here, so an FDA regulations exception would not apply in this case.

The ordinary FDA regulations exception requires some fact that undermines the rationale behind the learned intermediary

protect it from excess lest it becomes unworkable and alas, we find it replaced with something far less desirable." (quoting City of Philadelphia v. Lead Indus. Ass'n, Inc., 994 F.2d 112, 126 (3d Cir. 1993)). Further, at least one scholarly work agrees that other courts have "correctly rejected an FDA regulation exception to the learned intermediary doctrine." Charles J. Walsh et. al., The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling, 48 Rutgers L. Rev. 821, 873 (1996).

doctrine.[8] In jurisdictions where an FDA regulations exception has been adopted, it is applied "only if 'an in-depth analysis of the benefits and risks to the individual of the [drug's] administration appears to be unlikely.'" Yates v. Ortho-McNeil-Janssen Pharm., Inc., 808 F.3d 281, 292 (6th Cir. 2015) (quoting Samuels v. Am. Cyanamid Co., 495 N.Y.S.2d 1006 (N.Y. Sup. Ct. 1985)). Every court, except for one,[9] to adopt an exception based in part on FDA regulations has done so in the context of contraceptives—with most of these courts explicitly reasoning that an exception is appropriate in the contraceptives context because "the prescribing physician is relegated to a relatively passive role." MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69 (Mass. 1985).[10]

FDA regulations mandating direct-to-consumer warnings are not by themselves sufficient for the FDA regulations exception

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[8] For any exception, there must be some fact that undermines the rationale of the doctrine for the exception to apply. See Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971) (noting that the overpromotion exception would apply where the overpromotion "in effect cancelled out and rendered meaningless" the warnings provided to physicians), abrogated on other grounds by Kaczkowski v. Bolubasz, 421 A.2d 1027 (Pa. 1980).

[9] See Edwards v. Basel Pharm., 933 P.2d 298, 301 (Okla. 1997) (adopting a general FDA regulations exception to the learned intermediary doctrine based on cases recognizing an exception for contraceptives, with little reasoning behind the extension of FDA regulations exception to non-contraceptive cases).

[10] See also Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878 (E.D. Mich. 1985) ("The reasoning behind the rule of the learned intermediary—the reliance placed by the patient on the physician and interference with that relationship—simply does not hold up when the drug involved is an oral contraceptive."); Restatement (Third) of Torts: Prod. Liab. § 6 cmt. e. (1998) ("[W]arnings should be given directly to patients when the manufacturer is aware that health care medical providers will not be in a position to play the role of the learned intermediary.").

to apply. In the contraceptives context, "[a] majority of courts considering the question have held that the FDA regulations . . . should not serve as a basis to displace or create exceptions to the learned intermediary doctrine." Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 356 (Ill. 1996).[11] And no court has articulated a reason "[w]hy the learned intermediary doctrine should somehow be less applicable when the severity of the side effects encourages the FDA to promote additional labeling." In re Norplant Contraceptive Prod. Litig., 165 F.3d 374, 379 (5th Cir. 1999). So, in practice, the FDA regulations exception requires more than FDA regulations; it requires that a learned intermediary foreseeably would not play the traditional role in prescribing the drug.

Assuming Pennsylvania would adopt the FDA regulations exception,[12] it would similarly only apply the exception where it was foreseeable that a learned intermediary would not weigh the risks and benefits before prescribing the drug. Two cases illustrate this point.

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[11] See In re Norplant Contraceptive Prod. Liab. Litig., 955 F. Supp. 700, 704 (E.D. Tex. 1997), aff'd, 165 F.3d 374 (5th Cir. 1999) ("Only a single jurisdiction, Massachusetts, recognizes an exception to the doctrine for prescription contraceptives."); Prescription Drug Product Labeling, Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998) ("[C]ourts have not recognized an exception to the 'learned intermediary' defense in [other] situations where the FDA has required patient labeling.").

[12] That is not to say Pennsylvania would adopt this exception—in fact, the Superior Court might have already implicitly rejected this exception. See Taurino v. Ellen, 579 A.2d 925, 928 (Pa. Super. Ct. 1990) (refusing to find an exception to the learned intermediary doctrine for contraceptives, where the FDA mandated direct-to-consumer warnings).

First, the Third Circuit held in Mazur v. Merck & Co. that an exception to the learned intermediary doctrine would apply where it was foreseeable that a physician would not weigh the risks and benefits before prescribing the drug. 964 F.2d 1348 (3d Cir. 1992). In Mazur, the plaintiff was injured by a vaccination that was administered by a school nurse under a city-wide schoolchildren immunization program. Id. at 1350–51. The court assumed that Pennsylvania would adopt the mass immunizations exception and held that this exception would apply because the drug "was dispensed under 'clinic-like' conditions on the day [the plaintiff] was inoculated and it was foreseeable that the vaccine would be dispensed in this manner." Id. at 1364. It reasoned that "the rationale supporting the learned intermediary rule buckles where prescription drugs are dispensed without an individualized medical balancing of the risks and benefits to the user." Id. at 1361.

Second, the Pennsylvania Superior Court in Taurino v. Ellen held that an exception to the doctrine did not apply where it was not foreseeable that the drug would be dispensed without a physician's prescription. 579 A.2d 925, 928 (Pa. Super. Ct. 1990). In Taurino, the plaintiff was injured by a contraceptive provided at a clinic, not by a physician. Id. at 926. The court held that an exception to the learned intermediary doctrine did not apply because "the manufacturer ha[d] no reason

to know" that "someone other than a physician [would] administer[] the drug." Id. at 928.

This case is like Taurino, and it is unlike Mazur and the few cases finding a contraceptive exception. It was not foreseeable that the amiodarone would be administered without a learned intermediary weighing the risks and benefits. Indeed, there were at least three physicians that prescribed the drug to Joanne Polt after considering the risks and benefits of the drug. And the Polts point to nothing that made it foreseeable that the drug would be dispensed without a physician's considered prescription. Thus, following the reasoning of Taurino, Mazur, and the contraceptive exception cases, an FDA regulations exception would not apply in this case.[13]

iii. Negligence Per Se

The doctrine of negligence per se does not create new duties; rather, a claim alleging negligence per se must be based on a preexisting duty. And because the learned intermediary doctrine applies here and an exception does not, Sandoz had no duty to directly warn consumers. Thus, there is no preexisting

[13] Other courts have rejected an FDA regulation exception based on the medication guide requirement. See Small v. Amgen, Inc., 134 F. Supp. 3d 1358, 1369 (M.D. Fla. 2015) ("In fact, the courts that have addressed similar arguments have all concluded that the learned intermediary doctrine is not abrogated by the medication guide regulations.") (applying Florida law), aff'd, 723 F. App'x 722 (11th Cir. 2018); Hanhan v. Johnson & Johnson, No. 11-OE-40007, 2013 WL 5939720, at *3 (N.D. Ohio Nov. 5, 2013) ("[T]he Court agrees with those courts holding that the FDA regulations requiring direct patient warnings are an addition to-not a replacement of-states' learned intermediary rules.") (applying California law).

duty on which to base a negligence per se medication guide claim.

It is true that, although the FDCA does not create a private cause of action, a violation of the FDCA can form the basis for a negligence per se claim. Cabiroy v. Scipione, 767 A.2d 1078, 1081 (Pa. Super. Ct. 2001). That being said, where there is no preexisting tort duty, negligence per se does not operate to impose a new duty. In re Orthopedic Bone Screw Prod. Liab. Litig., 193 F.3d 781, 790 (3d Cir. 1999). So, whether there is a claim for negligence per se depends on if there is a duty under state law independent of the FDA regulations.[14]

Courts in Pennsylvania have only found a negligence per se claim based on the FDCA where the learned intermediary doctrine was not implicated. In Stanton v. Astra Pharm. Prods., Inc., the Third Circuit found a negligence per se claim where the drug manufacturer failed to comply with adverse effects reports regulations requiring reports to the FDA. 718 F.2d 553, 556,

[14] See Cuyler v. United States, 362 F.3d 949, 952 (7th Cir. 2004) ("But the statutory definition does not come into play unless the tort plaintiff establishes that the defendant owes a duty of care to the person he injured . . . because tort liability depends on the violation of a duty of care to the person injured by the defendant's wrongful conduct. . . . And although the legislature can and sometimes does create a duty of care to a new class of injured persons, the mere fact that a statute defines due care does not in and of itself create a duty enforceable by tort law."); accord Cabiroy v. Scipione, 767 A.2d 1078, 1081 (Pa. Super. Ct. 2001) ("[T]he doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort." (alteration in original) (quoting In re Orthopedic Bone Screw Prod. Liab. Litig., 193 F.3d 781, 790 (3d Cir. 1999))).

559–61 (3d Cir. 1983). Similarly, in Cabiroy, the Superior Court found a negligence per se claim where the drug manufacturer failed to comply with FDA drug approval requirements by distributing the drug to physicians without FDA approval. 767 A.2d at 1079. While Stanton and Cabiroy dealt with the drug approval process—and were thus outside of the orbit of the learned intermediary doctrine[15]—here, the warnings are at issue, and thus the learned intermediary doctrine is directly implicated.[16] And where the doctrine is implicated, there is no negligence per se claim for failure to provide a medication guide.

The Polts argue that their negligence per se claim is properly based on a general duty to warn. This argument fails because the learned intermediary doctrine specifically defines the drug manufacturers' duty to warn more narrowly. Pennsylvania courts have consistently held that the drug manufacturers' duty is defined by the learned intermediary

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[15] See Lance v. Wyeth, 85 A.3d 434, 457 (Pa. 2014) ("Accordingly, in a situation in which no warning would be sufficient, the learned intermediary doctrine should not apply to diminish the duties of pharmaceutical companies, or to insulate them from liability for a lack of due care.").

[16] The Superior Court also found negligence per se applied to a violation of the FDCA in In re Reglan/Metoclopramide Litig., where the defendant failed to update the label as required by the FDA. 81 A.3d 80, 94 (Pa. Super. Ct. 2013). Although the learned intermediary doctrine did apply in that situation, the regulations did not expand the duty beyond requiring the warning to the physician. Thus, there was no tension between the doctrine and allowing a claim under those regulations. But that is not case here, where the regulations are directly contrary to the learned intermediary doctrine.

doctrine and that they have no duty to warn consumers directly.[17] Further, the policy behind the doctrine shows that it defines the drug manufacturers' duty to warn such that a medication guide claim is not cognizable here. In adopting the doctrine, Pennsylvania has expressed the policy that the physician should be a gatekeeper: the physician, not the manufacturer, decides whether to prescribe drugs and explains the risks to consumers.[18] In other words, the Polts merely attempt to expand failure to warn liability and abrogate the learned intermediary doctrine under the guise of negligence per se.[19]

Therefore, there is no cognizable negligence per se claim for the failure of Sandoz to provide a medication guide to Joanne Polt.

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[17] See Stange v. Janssen Pharm., Inc., 179 A.3d 45, 57 (Pa. Super. Ct. 2018) (noting that "[t]he manufacturer has the duty to disclose risks to the physician, as opposed to the patient" under the learned intermediary doctrine (quoting Czimmer v. Janssen Pharm., Inc., 122 A.3d 1043, 1057 (Pa. Super. Ct. 2015))); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991) (noting that "the manufacturer has no duty to directly warn patients of the risks of drugs"); Taurino v. Ellen, 579 A.2d 925, 928 (Pa. Super. Ct. 1990) ("We cannot ignore them by imposing on manufacturers of contraceptive drugs an entirely new duty to warn patients directly, despite the clear limits of these prior decisions.").

[18] See Coyle, 584 A.2d at 1386 ("[Requiring pharmacies to warn consumers] would have the effect of undermining the physician-patient relationship by engendering fear, doubt, and second-guessing.").

[19] See Strayhorn v. Wyeth Pharm., Inc., 887 F. Supp. 2d 799, 817 (W.D. Tenn. 2012) (noting that all of the plaintiff's alternate theories of recovery—including negligence per se—were really just "failure to warn claims masquerading as other theories"), aff'd 737 F.3d 378 (6th Cir. 2013); In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 795, 814–15, 817 (N.D. Ohio 2004) (applying the learned intermediary doctrine because "attempt[ing] to shift the nature of the duty owed" by pleading negligence per se was a transparent attempt to expand the scope of a duty to warn theory beyond its true extent), aff'd sub nom. Meridia Prods. Liab. Litig. v. Abbott Labs., 447 F.3d 861 (6th Cir. 2006).

3. Breach of Duty

Last, the only claim that is not preempted—i.e., the claim that the physicians did not receive a warning at all—fails because there is no genuine dispute that the physicians received warnings that told them of the risks of amiodarone. The Polts contend that there is a genuine dispute of fact as to whether the physicians were warned because Dr. Cox claimed to not know that amiodarone was a drug of last resort and that it was not approved to treat non-life-threatening atrial fibrillation. But the drug manufacturer must "inform a physician of the facts which make the drug likely to be dangerous." Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super Ct. 2010). And there is no dispute that Dr. Cox or the other two doctors were aware that amiodarone carried the risk of pulmonary toxicity.[20]

B. The Polts' Cross-Motions for Partial Summary Judgment

The Polts' cross-motions for partial summary judgment are denied for the same reason that Sandoz's motion is granted: the drug manufacturers do not have a duty to warn consumers directly. The Polts' cross-motion for partial summary judgment on the learned intermediary doctrine fails because neither an abandonment of nor an exception to the doctrine is appropriate

[20] It is irrelevant that Dr. Cox did not testify that he unequivocally understood the warning because the adequacy of the warning is not at issue since a claim that the warning was inadequate is preempted. See PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011) (holding that claims for inadequate warnings against generic manufacturers are preempted).

here. The Polts' cross-motion for partial summary judgment on the adequacy of the warning fails because it assumes that Sandoz has a duty to warn consumers directly, but this assumption is incorrect.

In sum, it is not for the Court to locate a new exception to the learned intermediary doctrine where the state courts have found none. And in any event, an exception based on the FDA's medication guide regulations, even if the Pennsylvania Supreme Court were to adopt it, would not apply here because it was foreseeable that Joanne Polt would consume the drug following her physician's considered prescription.[21]

V. CONCLUSION

For the foregoing reasons, Sandoz's Motion for Summary Judgment will be granted and the Polts' Cross-Motions for Summary Judgment will be denied. An appropriate Order follows.

[21] To the extent the Polts seek to establish liability for the alleged inadequacy of the warning to physicians, this claim is preempted. And to the extent they argue that the physicians were not given the required warnings, this argument is refuted by the evidence: Dr. Cox's testimony—which is the only testimony the Polts point to as creating a dispute of fact that warnings were given—shows that Dr. Cox received the warnings about the risks of amiodarone because he knew of the risk of pulmonary toxicity.